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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,319	02/17/2006	Michel Drancourt	123296	8564

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EXAMINER	
THOMAS, DAVID C	
ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,319	DRANCOURT ET AL.	
	Examiner	Art Unit	
	DAVID C. THOMAS	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-12,15,16,18 and 22-24* is/are pending in the application.

4a) Of the above claim(s) *15,16,18 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-12,23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response in a Supplemental Amendment filed January 16, 2009 is acknowledged. Claims 1-4 (currently amended), claims 7-12 (previously presented) and claims 23 and 24 (newly added) will be examined on the merits. Claims 11, 16, 18 and 22 were previously withdrawn and claims 18 and 22 are also currently amended. Claims 5, 6, 13, 14, 17 and 19-21 were previously canceled. The further election of SEQ ID NOS: 20, 24, 29 and 30 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-4, 7-12, 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Part (c) of claims 1-4, is drawn to an isolated rpoB gene or gene fragment specific to the bacterium genus *Streptococcus* or the related genus *Enterococcus* comprising a nucleic acid sequence having 98.7% homology to the elected SEQ ID NOS: 1 or 8-10, 13, 15, 16, 20, 24, 29 and 30 or sequences complementary to SEQ ID NOS: 1 or 8-10, 13, 15, 16, 20, 24, 29 and 30. The instant specification only describes

the nucleic acids comprising SEQ ID NOS: 1, 8-10, 13, 15, 16, 20, 24, 29 and 30. Applicants did not adequately describe a representative number of sequences having 98.7% homology to the elected SEQ ID NOS: 1, 8-10, 13, 15, 16, 20, 24, 29 and 30 or complementary sequences. In fact, only a limited number of sequences was provided, that of SEQ ID NO: 1, 8-10, 13, 15, 16, 20, 24, 29 and 30. With regard to claim 4, Applicants did not adequately describe a representative number of oligonucleotide sequences having 98.7% homology to sequences having at least 20 consecutive nucleotides of the elected SEQ ID NO: 8-10, 13, 15, 16, 20, 24, 29 and 30 or complementary sequences. In fact, only a limited number of sequences was provided, that of SEQ ID NO: 8-10, 13, 15, 16, 20, 24, 29 and 30. Similarly, part (c) claims 23 and 24 are drawn to a set of isolated oligonucleotides comprising sequences having at least 99.3% homology to SEQ ID NOS: 8-35 or sequences complementary to SEQ ID NOS: 8-35. Applicants did not adequately describe a representative number of sequences having 99.3% homology to the elected SEQ ID NOS: 8-35 or complementary sequences, but rather only a limited number of sequences was provided, that of SEQ ID NOS: 8-35.

For example, a polynucleotide comprising a sequence with 98.7% sequence identity to SEQ ID NO: 1 would contain 4462 bp identical to SEQ ID NO: 1. If the polynucleotide was 4523 bp long, it would have 59 bp different from SEQ ID NO: 1. Considering that each of the 59 bp can be one of four bases, the number of sequences of 4523 bp 98.7% identical to SEQ ID NO: 1 would be 4^{59} or about 3.3×10^{35} sequences. Since there is no limit on the length of such polynucleotides, the number of

such molecules is in the order of billions of billions. Similarly, a polynucleotide comprising a sequence with 98.7% sequence identity to SEQ ID NO: 8 would contain 700 bp identical to SEQ ID NO: 8. If the polynucleotide was 709 bp long, it would have 9 bp different from SEQ ID NO: 8. Considering that each of the 9 bp can be one of four bases, the number of sequences of 709 bp 98.7% identical to SEQ ID NO: 8 would be 4^9 or about 2.6×10^5 sequences. Since there is no limit on the length of such polynucleotides, the number of such molecules is also in the order of billions.

With regard to claims 7-12, Applicants did not adequately describe a representative number of oligonucleotide sequences comprising a sequence including at least 8 consecutive nucleotides of SEQ ID NOS: 6 or 7 or sequences complementary to sequences comprising a sequence including at least 8 consecutive nucleotides of SEQ ID NOS: 6 or 7. In fact, only two sequences were provided, that of SEQ ID NOS: 6 and 7, comprising degenerate bases or inosine at selected positions.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that “Satisfactory disclosure of a “representative number” depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed.” (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of nucleic acids which are different from those disclosed in the specification. With regard to claims 1-4, the genus includes nucleic acid variants for which no written description is provided in the specification, since sequences either need only to have at least 98.7% homology to SEQ ID NOS: 1 or 8-10, 13, 15, 16, 20, 24, 29 and 30 or complementary sequences, but could also contain additional completely unrelated sequences of unlimited length. This large genus is represented in the specification by only the particularly named SEQ ID NO: 1, 8-10, 13, 15, 16, 20, 24, 29 and 30. With regard to claims 23 and 24, the genus includes nucleic acid variants for which no written description is provided in the specification, since sequences either need only to have at least 99.3% homology to SEQ ID NOS: 8-35 or complementary sequences, but could also contain additional completely unrelated sequences of unlimited length. This large genus is represented in the specification by only the particularly named SEQ ID NOS: 8-35. With regard to claims 7-12, the genus also includes nucleic acid variants for which no written description is provided in the specification, since sequences either need only to have 8 consecutive nucleotides of SEQ ID NOS: 6 or 7 or complementary sequences, but could also contain additional completely unrelated sequences comprised in the oligonucleotides, which may be up to 100 bp in total length. This large genus is represented in the specification by only the particularly named SEQ ID NO: 6 with 20 nucleotides and SEQ ID NO: 7 with 23 nucleotides. Thus, applicant has express possession of only four particular sequences, in a genus which comprises billions of different possibilities.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

> "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of the nucleic acid sequences from claims 1-4 (c), 7-12 and 23 (c) and 24 (c) lack any specific structure, and is precisely the situation of naming a type of material which is generally known to likely exist, but, except for the four specific sequences, is in the absence of knowledge of the material composition and fails to provide descriptive support for the claims.

In the instant application, certain specific SEQ ID NOS are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly

disclosed which comprise SEQ ID NOS: 1 and 6-35. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3, 4 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Doucette-Stamm et al. (U.S. Patent No. 6,583,275).

With regard to claims 1, 3 and 23, Doucette-Stamm teaches an isolated *rpoB* gene fragment of the genus *Streptococcus* or the related genus *Enterococcus* comprising a nucleic acid sequence selected from the group consisting of:

(c) sequences having at least 98.7% homology to the sequences of SEQ ID NOS: 8-10, 13, 15, 16, 20, 24, 29 and 30 (positions 1696-970 of SEQ ID NO: 848 taught by Doucette-Stamm representing sequences of *Enterococcus faecium* are 99.7% homologous to positions 1-726 of SEQ ID NO: 29, containing only two mismatched bases over that span).

With regard to claim 4, Doucette-Stamm teaches an isolated oligonucleotide comprising:

(a) a nucleic acid sequence specific to a bacterium of the genus *Streptococcus* or of the related genus *Enterococcus,* and comprising 20-100 consecutive nucleotides included in one of the nucleic acid sequences set forth in SEQ ID NOS: 8-10, 13, 15, 16, 20, 24, 29 and 30 (positions 1696-970 of SEQ ID NO: 848 taught by Doucette-Stamm representing sequences of *Enterococcus faecium* are 99.7% homologous to positions 1-726 of SEQ ID NO: 29, containing only two mismatched bases over that span).

6. Claim 4 is rejected under 35 U.S.C. 102(e) as being anticipated by Doucette-Stamm et al. (U.S. Patent No. 6,617,156).

With regard to claim 4, Doucette-Stamm teaches an isolated oligonucleotide comprising:

(a) a nucleic acid sequence specific to a bacterium of the genus *Streptococcus* or of the related genus *Enterococcus,* and comprising 20-100 consecutive nucleotides included in one of the nucleic acid sequences set forth in SEQ ID NOS: 8-10, 13, 15, 16, 20, 24, 29 and 30 (positions 1717-1002 of SEQ ID NO: 2197 taught by Doucette-Stamm representing sequences of *Enterococcus faecium* are 99.0% homologous to positions 1-715 of SEQ ID NO: 30, containing only seven mismatched bases over that span).

7. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Haselbeck et al. (U.S. Patent Pub. No. 2002/0061569).

With regard to claim 4, Haselbeck teaches an isolated oligonucleotide comprising:

(a) a nucleic acid sequence specific to a bacterium of the genus *Streptococcus* or of the related genus *Enterococcus,* and comprising 20-100 consecutive nucleotides included in one of the nucleic acid sequences set forth in SEQ ID NOS: 8-10, 13, 15, 16, 20, 24, 29 and 30 (positions 2278-2309 of SEQ ID NO: 9089 taught by Haselbeck representing sequences of *Streptococcus pneumoniae* are 100% homologous to positions 1-32 of SEQ ID NO: 8, a span of 32 consecutive nucleotides; in addition, positions 2548-2603 of SEQ ID NO: 9089 are 100% homologous to positions 271-326 of SEQ ID NO: 8, a span of 56 consecutive nucleotides).

8. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Kunsch et al. (U.S. Patent No. 6,420,135).

With regard to claim 4, Kunsch teaches an isolated oligonucleotide comprising:

(a) a nucleic acid sequence specific to a bacterium of the genus *Streptococcus* or of the related genus *Enterococcus,* and comprising 20-100 consecutive nucleotides included in one of the nucleic acid sequences set forth in SEQ ID NOS: 8-10, 13, 15, 16, 20, 24, 29 and 30 (positions 11613-11582 of SEQ ID NO: 111 taught by Kunsch representing sequences of *Streptococcus pneumoniae* are 100% homologous to positions 1-32 of SEQ ID NO: 8, a span of 32 consecutive nucleotides; in addition,

positions 11343-11288 of SEQ ID NO: 111 are 100% homologous to positions 271-326 of SEQ ID NO: 8, a span of 56 consecutive nucleotides).

Response to Arguments

9. Applicant's arguments filed January 16, 2009, as well as those filed June 23, 2008, have been fully considered but they are not persuasive.

Applicant previously argued that the rejection of claims 1-4 and 7-12 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, should be withdrawn based, in part, on amendments of claims 1-4 (b) to require "full-length complementary sequences". The Examiner agrees that with this amendment, claims 1-4 (b) now comply with the written description requirement. Applicant further argued that part (c) of claims 1-4 was also in compliance since "sequences having at least 98.7% homology" are restricted by other claims limitations. The Examiner asserts that the other claim limitations do not preclude a very large number of sequences based not only on the significant number of nucleotide differences a sequence with 98.7% relative to the full-length sequence would have, but also the fact that the sequence could be of any length beyond that represented by the SEQ ID NOS: 8-10, 13, 15, 16, 20, 24, 29 and 30. Finally, there is no rebuttal regarding the written description rejection of claims 7-12 and therefore the rejection of claims 1-4 and 7-12 and new claims 23 and 24 under 35 U.S.C. 112, first paragraph is maintained.

With regard to amended claims 1-4 and newly added claims 23 and 24, Applicant's arguments with respect to the previous 102(b) prior art rejections of record

have been noted, but are moot in view of the rejection of the claims based on new grounds. Note: the claims are drawn to a product and therefore a sequence in the prior art that matches the claimed sequence anticipates the claim, regardless of the source of the prior art sequence.

Conclusion

10. Claims 1-4, 7-12, 23 and 24 are rejected. No claims are allowable. However, with regard to claim 2, no prior art was found that teaches an isolated *rpoB* gene comprising a nucleic acid sequence of SEQ ID NO: 1. In addition, with regard to claims 7-12, no prior art was found that teaches equimolar mixtures of oligonucleotides as defined in claim 7, with each having a different sequence. Finally, with regard to claim 24, no prior art was found that teaches a set of oligonucleotides comprising the full-length sequences and complementary sequences to those set forth in SEQ ID NOS: 8-35 and sequences having at least 99.3% homology to these sequences.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Thomas whose telephone number is 571-272-3320 and whose fax number is 571-273-3320. The examiner can normally be reached on 5 days, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David C Thomas/
Examiner, Art Unit 1637

/Teresa E Strzelecka/

Primary Examiner, Art Unit 1637

March 12, 2009